September 28, 2017

Olympus Winter & Ibe GmbH
% Dolan Mills
Sr. Specialist, Regulatory Affairs
Gyrus ACMI, Inc.
136 Turnpike Road
Southborough, MA 01772

Re: K171965
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: II
Product Code: FAS, FJL, HIH
Dated: June 29, 2017
Received: June 30, 2017

Dear Dolan Mills:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of
devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Charles Viviano -S

For Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal, and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K171965

Device Name

Indications for Use (Describe)
Electrodes with HF-cable are part of a resectoscope system for endoscopic diagnosis and treatment in urological applications: Cutting, ablation, resection, vaporization and coagulation with HF current.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)  ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Indications for Use

Electrodes with HF-cable are part of a resectoscope system for endoscopic diagnosis and treatment in gynecological applications.

The general indications include transcervical resection, vaporization, ablation, cutting and coagulation of tissue in the uterus in conductive irrigation fluid as part of a resectoscope system.

Specific indications:
- transcervical diagnosis and treatment (resection, vaporization, ablation, biopsy, cutting and coagulation) of intrauterine myomas, intrauterine polyps, synechias and endometrium (TCRis)
- lysis of intrauterine septa
- endometrial ablation

Type of Use (Select one or both, as applicable)

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
K171965
510(k) Summary of Safety and Effectiveness
September 22, 2017

1. General Information

Manufacturer: Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Germany

Establishment Registration Number: 9610773

Official Correspondent: Dolan Mills
Sr. Specialist, Regulatory Affairs
Gyrus ACMI, Inc.
136 Turnpike Rd.
Southborough, MA 01772-2104
Phone: 901.373.0236
Fax: 901.373-0220
Email: dolan.mills@olympus-osta.com

Establishment Registration No 3003790304

2. Device Identification

Common Name: Electrode, Electrosurgical, active, urological
Regulation Number: 876.4300
Classification: Endoscopic electrosurgical unit and accessories
Device Class: II
Product Code: FAS / HIH / FJL
Review Panel: Gastroenterology / Urology / Obstetrics / Gynecology
Proprietary/Trade Name: Resection Electrodes with HF cable

Model numbers:
WA22702S, WA22703S, WA22705S, WA22706S, WA22707S, WA22721S,
WA22723S, WA22732S, WA22737S, WA22738S, WA22739S, WA22751S,
WA22755S, WA22760S, WA22602S, WA22603S, WA22605S, WA22606S,
WA22607S, WA22621S, WA22623S, WA22632S, WA22637S, WA22638S,


3. Predicate Devices

The predicate device was chosen from the following predicate 510(k):

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These predicates have not been subject to a design-related recall.

No reference devices were used in this submission.
4. Product Description

The Olympus Resection Electrodes with HF cable that are subject to this submission are for application in saline. Depending on the characteristics of electrical current, which is provided by the electrosurgical generator, electrosurgery can be used for coagulation, vaporization and cutting.

The subject HF-Resection Electrodes consist of an active tip, PTFE color code identification, an insulator between the electrode and electrode tube, a guiding tube, telescope clip and arm (shaft). The accompanying HF cables consist of two lantern plugs on the instrument side and one generator plug on the generator side.

The design and dimensions of the electrodes vary to accommodate various procedural conditions. The active tips of the various electrodes may consist of loops, bands, rollers, needles or buttons. The electrodes have a shaft diameter of 24 Fr, range in length from 261.8-336.7mm, and range in compatibility with telescopes with a direction of view of 12° - 30°. The design of the HF cable plugs vary depending on which electrosurgical generator they are compatible with.

All subject Resection Electrodes are single-use electrodes and are delivered sterile.
All subject Resection Electrodes are provided with a single-use, sterile cable to connect the electrode to the generator.

5. Indications for Use

Resection Electrodes with HF cable for use in Urology

Electrodes with HF-cable are part of a resectoscope system for endoscopic diagnosis and treatment in urological applications: Cutting, ablation, resection, vaporization and coagulation with HF current.

Resection Electrodes with HF cable for use in Gynecology
Electrodes with HF-cable are part of a resectoscope system for endoscopic diagnosis and treatment in gynecological applications.

The general indications include transcervical resection, vaporization, ablation, cutting and coagulation of tissue in the uterus in conductive irrigation fluid as part of a resectoscope system.

Specific indications:

- transcervical diagnosis and treatment (resection, vaporization, ablation, biopsy, cutting and coagulation) of intrauterine myomas, intrauterine polyps, synechias and endometrium (TCRis)
- lysis of intrauterine septa
- endometrial ablation

Although the subject and predicate devices have different indications for use statements, the intended use is the same. The subject device is indicated for gynecologic applications while the predicate device is indicated for urological indications. However, when the decision-making criteria specified in the FDA guidance document, “General/Specific Intended Use,” (issued November 4, 1998) are applied, the subject device indications are determined to fall within the scope of the intended use of the predicate device. The specific gynecology indications of the subject device do not represent a different intended use since there is an extensive knowledge base regarding the use of bipolar electrosurgery for gynecological applications, including the disease states listed in the specific gynecologic indications. Therefore, the intended use comparison supports substantial equivalence.

6. Comparison of Technological characteristics

At a high level, the subject and predicate devices are based on the same technological principle with the same elements:

- Resection electrodes consisting of an active (distal) tip, PTFE color code identification at the distal and proximal ends, an insulator between the electrode and electrode tube, a stabilizing (guiding) tube, and arm (shaft)
- HF cables consisting of two lantern plugs on the instrument side and one generator plug on the generator side
- Used in combination with a resectoscope system
- Like the predicate electrodes, the subject device resection electrode series features loops, bands, needles, rollers, and a button as active tip shapes
- Resection electrodes utilizing ablation or for resection in saline (dependent on model)
- Respectively identical or similar outer dimensions
- Design changes of the electrodes and cables are minor and do not negatively impact safety or effectiveness of the subject devices
- The same or similar materials in patient contact are used in predicate and subject device and have all been successfully tested for biocompatibility.

As stated above, the subject and predicate devices have similar design characteristics and performance specifications, with the exception of the addition of the HF cables. These minor differences, however, do not raise different questions of safety or effectiveness. As demonstrated in the non-clinical testing (e.g., electrical safety, sterilization validation, and package integrity), the different technological characteristics do not affect the safety and effectiveness of the subject devices.

7. Performance Data

The subject device electrodes, including all patient-contacting materials, are identical in design and manufacturing to the predicate device (K152092). Therefore, the current submission relies on performance testing previously reviewed and deemed acceptable in K152092.

8. Electrical safety and electromagnetic compatibility (EMC)

Electrical Safety was tested according to

Medical Electrical Equipment - Part 1.1 General requirements for safety and essential performance.

AAMI/ANSI/IEC 60601-2-2 2009
Medical Electrical Equipment - Part 2-2: Particular Requirements for the Basic Safety And Essential Performance of High Frequency Surgical Equipment and High Frequency Surgical Accessories

IEC 60601-2-18:2009
Medical electrical equipment - Part 2-18: Medical Electrical Equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.

Electromagnetic compatibility (EMC) testing according to IEC 60601-1-2 and IEC 60601-2-2 is not applicable to the Resection Electrodes. They do not contain any electrical components that can be influenced by electromagnetic emission as well as electrostatic discharge. From an electromagnetic compatibility point of view, it is a metal bar that cannot be influenced at any time.
9. Sterilization and Shelf Life
Sterilization is performed according to ISO 11135 and packaging conforms with AAMI ANSI ISO 11607-1:2006. The EtO sterilization cycle has been validated.

A sterility assurance level (SAL) of $10^{-6}$ was reached during validation and will be used for routine sterilization in compliance with regulations in force for sterile medical devices.

The EtO residuals are within the limits after tunnel degassing time.

Shelf Life testing, including package integrity testing in accordance with ISO 11607-1:2006, was conducted to support a shelf life of 3 years for the resection electrodes.

10. Conclusion

The performance data support the safety and effectiveness of the subject device and demonstrate that the subject device is substantially equivalent to the predicate device.

In conclusion, the Resection Electrodes with HF cable are substantially equivalent to the predicate devices.